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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,150	08/30/2006	Jean-Francois Butty	MEMI-2	6130

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EXAMINER	
HUPCZEY, JR, RONALD JAMES	
ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
10/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,150	BUTTY ET AL.	
	Examiner	Art Unit	
	RONALD J. HUPCZEY, JR.	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *22-24* is/are allowed.

6)☒ Claim(s) *13-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and arguments, received on July 24th, 2009, have been fully considered by the examiner. Claims 13-24 are currently pending with claims 13, 19 and 22 amended. Applicant's amendment to claim 22 obviates the previously filed rejection of claims 22-24 under 35 U.S.C 112 second paragraph. The following is a complete response to the July 24th, 2009 communication.

Claim Rejections - 35 USC § 112

2. Claims 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 13 and 19, Applicant has set forth that a first pair of electrodes are to function in a bipolar mode and a second pair of electrodes are to function in a monopolar mode. While Applicant now positively recites (by the removal of "adapted to") how each electrode is intended to function, the claims as currently written, lack recitation of the necessary structure to perform the function. As such, the claims are being rejection for being incomplete due to the omission of essential element(s), where such an omission amounts to a gap between the elements. See MPEP § 2172.01. The omitted element(s) are: a source of monopolar and/or bipolar energy connected to the electrodes.

Claims 14-18 and 20-21 are rejected due to their respective dependency on claims 13 and 19.

Claim Rejections - 35 USC § 103

3. Claims 13-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Champeau (US Pat. No. 6,208,881 B1) in view of Tu et al (US Pat. No. 5,938,659) and Eggers et al (US Pat. No. 6,312,428).

Regarding claim 13, Champeau discloses a catheter (catheter **10**) containing at least one pair of electrodes capable of functioning in a bipolar manner and at least two end electrodes arranged towards opposed ends of the catheter on either side of the pair of aforementioned electrodes capable of functioning in a monopolar manner (electrodes **30**, **32**, **34**, **36**, **38**). Champeau further discloses a plurality of supply channels (apertures **68**) capable of perfusing saline solution around the electrodes (see col. 8, lns. 4-9). Champeau fails to specifically recite the limitation of a pointed tip for piercing insertion and for the plurality of supply channels to be contained with the area defined by the bipolar electrodes. Tu discloses a similar catheter containing a plurality of electrodes and further discloses the electrodes to contain supply channels for the perfusion of saline solution around the electrodes (hollow passage **20**, see col. 7; 17-27). Tu fails to discloses the inclusion of a sharp tip on the catheter. Eggers discloses a similar device to that of Champeau and Tu containing a plurality of electrodes functioning in an electrosurgical manner. Eggers further discloses the inclusion of a sharp tip on a catheter to facilitate the placement of the device in a target portion of tissue (see figures 2A, 3 and 7; col. 7; 18-24). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Champeau with a sharp tip and a plurality of supply channels containing within the bipolar electrodes. The inclusion of a sharp tip is something old and well known in the art which allows for easier insertion of the catheter into the target tissue.

Furthermore, as evidenced by Eggers, such a sharp distal tip is utilized with structures containing a plurality of distal electrodes. Additionally, the provision of the supply channels being contained in the bipolar electrodes, as evidenced by Tu provides for the perfusion of a fluid directly to the area around the electrodes ensuring that a treatment fluid is present in the area surrounding the electrode. Lastly, both the provisions of Tu and Eggers can be provided on the device of Champeau by common fabrication methods known to one of ordinary skill in the art.

Regarding claim 14, Champeau fails to disclose the bipolar electrodes at least two saline solution supply channels (lumen **66**). Tu in view of the above rejected claim 13 provides for at least two supply channels per electrode (see figures 3 and 5). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for a similar number of supply channels in each electrode as that of Tu on the device of Champeau in order to facilitate the perfusion of a liquid to the area surrounding each electrode.

Regarding claim 15, Champeau discloses liquid supply channels (lumen **66**) with outlets (bores **68**) arranged near the front and rear ends of the catheter and for the supply of a treatment liquid to be capable of being supplied to any of the outlets independent of the other outlets (see col. 8, lns. 4-12).

Regarding claim 16, Champeau discloses a plurality of electrodes (electrodes **30**, **32**, **34**, **36**, **38**) disposed on the catheter body with electrode (electrode **34**) arranged between two other electrodes (see figure 1). Champeau further discloses for the electrode to be capable of supplying monopolar energy (see col. 3, lns. 30-34).

Regarding claim 18, in view of the above rejected claims 13 and 16, it would have been obvious to one of ordinary skill in the art at the time the invention was made that with the supply

channels placed in view of Tu on the bipolar electrodes would possess a an arbitrary distance from the monopolar electrode which is sufficient to avoid being in a region of coagulated tissue formed around the monopolar electrodes.

Regarding claim 19, Champeau discloses a catheter (catheter **10**) containing at least one pair of electrodes capable of functioning in a bipolar manner and at least two end electrodes arranged towards opposed ends of the catheter on either side of the pair of aforementioned electrodes capable of functioning in a monopolar manner (electrodes **30**, **32**, **34**, **36**, **38**). Champeau further discloses a plurality of supply channels (apertures **68**) capable of perfusing in an individually controllable manner, saline solution around the electrodes (see col. 8, lns. 4-12). Champeau fails to specifically recite the limitation of a pointed tip for piercing insertion, for the plurality of supply channel to be contained with the area defined by the bipolar electrodes or for the inclusion of two pumps to supply the saline to the bipolar electrodes. Tu discloses a similar catheter containing a plurality of electrodes and further discloses the electrodes to contain supply channels for the perfusion of saline solution around the electrodes (hollow passage **20**, see col. 7; 17-27). Tu fails to disclose the inclusion of a sharp tip on the catheter. Eggers discloses a similar device to that of Champeau and Tu containing a plurality of electrodes functioning in an electrosurgical manner. Eggers further discloses the inclusion of a sharp tip on a catheter to facilitate the placement of the device in a target portion of tissue (see figures 2A, 3 and 7; col. 7; 18-24). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Champeau with a sharp tip and a plurality of supply channels containing within the bipolar electrodes. The disclosure by Champeau of the individual control of the supply of liquid would require multiple pumping/supply means to allow for

selective delivery of saline solution as well as individual control of injection rate. The inclusion of a sharp tip is something old and well known in the art which allows for easier insertion of the catheter into the target tissue. Furthermore, as evidenced by Eggers, such a sharp distal tip is utilized with structures containing a plurality of distal electrodes. Additionally, the provision of the supply channels being contained in the bipolar electrodes, as evidenced by Tu provides for the perfusion of a fluid directly to the area around the electrodes ensuring that a treatment fluid is present in the area surrounding the electrode. Lastly, both the provisions of Tu and Eggers can be provided on the device of Champeau by common fabrication methods known to one of ordinary skill in the art.

Regarding claim 20, Champeau discloses a temperature acquisition unit (microprocessor-based control system, see col. 8, lns. 24 – 30) connected to the thermocouples within the catheter.

4. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Champeau (US Pat. No. 6,208,881 B1) in view of Tu et al (US Pat. No. 5,938,659) and Eggers et al (US Pat. No. 6,312,428) and further in view of Houser et al (US Pub. No. 2002/0035361 A1).

Regarding claim 17, in view of the above rejected claim 13 Champeau discloses thermocouples disposed within the catheter tip and functioning to measure the temperature of the surrounding tissue. Tu additionally discloses the inclusion of a temperature sensor associated with the distal end of the disclosed device to assess the temperature of the tissue. Champeau, Tu and Eggers fails to disclose the thermocouples to be retractably mounted in the catheter. Houser et al discloses a catheter containing a plurality of central bores (**146**) and side bores (**148**) with temperature sensors (**150**) retractably disposed within the bores (see paragraph [0086]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the retractable temperature sensors disclosed by Houser et al with the above described device of rejected claim 13 to allow for a catheter with sensing means insertable into the surrounding tissue. Each invention is directed towards the same inventive concept radiofrequency ablation to tissue with temperature monitoring and the disclosed structure of Champeau in view of Tu and Eggers readily allows for such temperature sensors of Houser et al to be disposed within the catheter. The combination would further provide for a device which can sense temperature at increased depth sin the surrounding tissue thereby allow for greater control and assessment of the treatment progress.

Allowable Subject Matter

5. Claims 22-24 are allowed.

6. Claim 21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: While Champeau in view of the disclosure of Mulier et al (US Pat. No. 6,537,248 B2) represents the closet prior art of record, neither discloses or provides for a combination which provides for each of the limitations presented in claim 22. Additionally, in view of applicant's remarks filed October 20th, 2008, none of the prior art of record sets forth a method of radiofrequency ablation wherein the electrical power is first supplied to the monopolar electrodes to seal the puncture caused by the catheter such that the tissue forms a seal with the catheter. The prior art of record

additionally fails to provide for the perfusing of saline into the now sealed portion of tissue and the subsequent supply of bipolar RF energy in order to effectuate thermal ablation.

Response to Arguments

8. Applicant's arguments filed July 24th, 2009 have been fully considered but they are not persuasive.

Regarding Applicant's arguments that the amendment to the language in claims 13 and 19 now specifies in definite terms the functions of the respective electrodes, the Examiner respectfully disagrees that such a positive recitation is now present in the claims. Applicant's attention is first drawn to the rejection above of claims 13-21 under 35 U.S.C. 112, 2nd paragraph for being indefinite due to the omission of essential subject matter in claims 13 and 19. The claim, while reciting a first pair of electrodes to function in a bipolar mode and a second pair of electrodes to function in a monopolar mode, fails to set forth connection to any source of electrosurgical energy in order to provide the specific function of each pair of electrodes. An electrode, until connected to a source of energy is just an electrode regardless of what it is named and/or called. While Applicant may claim that two electrodes are a "pair of bipolar electrodes" or a "pair of monopolar electrodes", there is no substantive difference between the electrodes until they are connected to a source of energy which allows each pair of electrodes to perform its intended use. As a result, the nomenclature used in both claims 13 and 19 will still be interpreted as merely a recitation of intended use and it is noted that such limitations fail to structurally distinguish the claims from the prior art of record, which is capable of being used as desired. Since the prior art structure is capable of performing the intended use, then it meets the claim. In

each instance that a statement of intended use is relied upon, the same standard as mentioned above will be applied.

Regarding Applicant's argument that rejection of claim 13 employs impermissible hindsight reasoning, the Examiner respectfully disagrees. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The Examiner maintains the position that one of ordinary skill in the art at the time the invention was made would appreciate that the inclusion of a pointed tip would be an obvious design choice (as evidenced by Eggers) when designing such a catheter and such an inclusion would only require routine skill in the art. Furthermore, a pointed tip is a well known and commonly utilized feature on catheters containing multiple electrodes and such a feature would be appreciated by one of ordinary skill as something which **would not** distinguish the instant invention from the prior art of record. While the use of a pointed tip in a catheter designed for navigation within a body lumen certainly, one of ordinary skill would recognize that in designing a catheter for puncturing or penetrating that tip which allows for such a function (i.e. pointed tip) would be apparent consideration for the tip of the catheter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD J. HUPCZEY, JR. whose telephone number is (571)270-5534. The examiner can normally be reached on Mon. - Fri. from 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD J HUPCZEY, JR./
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH